New Drug Shows Improvement in Depression Scores Within 24 Hours

Naurex, Inc., announced that a single intravenous dose of NRX-1074 resulted in a statistically significant improvement in depression scores within 24 hours in a phase II single-dose study in patients with major depressive disorder (MDD).

At the highest and most effective dose level, the average reduction in Hamilton Depression Rating Scale (HDRS)-17 scores at 24 hours was 14 points, with a mean difference from a placebo of 7 points (\( p = 0.0029 \)). The effect size observed at 24 hours after dosing was 0.88—more than double the size seen with most other antidepressant drugs after 4 to 6 weeks of repeated dosing. Seventy-two percent of patients receiving the highest dose demonstrated a clinically meaningful response at 24 hours compared to 39% of patients given a placebo (\( p = 0.038 \)).

In the study, which enrolled approximately 140 patients, NRX-1074 was well-tolerated, with no drug-related serious adverse events reported and no patients dropping out due to adverse events.

The study was conducted at 12 clinical centers in the United States. Patients received one of three dose levels of NRX-1074 or a placebo. The primary clinical efficacy measure was the HDRS-17, which was administered by off-site independent raters who were blinded to the protocol to ensure the quality and objectivity of the rating data. Safety was also assessed.

Priority Review Granted for New Drug Treatment of Schizophrenia

Janssen Research & Development announced that the U.S. Food and Drug Administration has granted Priority Review for the New Drug Application for 3-month atypical antipsychotic paliperidone palmitate to treat schizophrenia in adults. If approved, it will be the first and only long-acting atypical antipsychotic agent that has a dosing schedule of just four times per year.

The filing was based on a phase III, international, randomized, multicenter, double-blind, relapse prevention study of paliperidone palmitate 3-month injection. The study, which included more than 500 patients, evaluated the efficacy of 3-month paliperidone palmitate compared with a placebo in delaying time to first occurrence of relapse symptoms of schizophrenia. Patients who were randomized to treatment were stabilized with Invega® Sustenna®, an approved treatment for schizophrenia, prior to receiving the investigational 3-month formulation. The study was stopped early for positive efficacy after an interim review of the data by an independent data monitoring committee based on pre-specified criteria. The safety profile of paliperidone palmitate 3-month formulation is consistent with that of once-monthly Invega Sustenna.